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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/499,693	02/08/2000	Insu Lee	00120/P-4858	1622

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EXAMINER	
MITCHELL, GREGORY W	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/499,693	LEE ET AL.	
	Examiner	Art Unit	
	Gregory W. Mitchell	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/14/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Remarks and Amendments filed July 07, 2005. Claims 26, 28-29, 32-38, 40-42 and 44-45 have been amended. Claims 26-45 are pending and are examined herein.

Applicant's Amendments have necessitated the withdrawal of the previous Office Action. The following rejections now apply.

It is noted that the limitation of a daily dose of 0.15 to 0.3 g/kg finds support in the specification as originally filed on page 5. Daily dosages of 9-18 grams per 60 kg body weight are taught and are equivalent to those doses as claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-29, 32-33, 36-37, 40-41 and 44-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This is a **NEW MATTER** rejection. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has amended the claims to include a new linoleic to α-linolenic weight ratio range of 0.5-2.0. This recitation does not find support in the Application as originally filed. As filed, the Application only provides support for the

ranges of 0.05-7.5 and, more preferably, 0.05-2.0. It is noted that a genus does not support a subgenus even though there is a disclosed species within the subgenus. *In re Smith*, 173 USPQ 679 (CCPA 1972). Disclosure in an application that merely renders the later-claimed invention obvious is not sufficient to meet the written description requirement of 35 USC 112(1). *Lockwood v. American Airlines, Inc.*, 41 USPQ.2d 1961 at 1966 (CAFC 1997).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-29, 32-33, 36-37 and 40-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28-29, 32-33, 36-37 and 40-41 recite the limitation "said food". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26, 28, 34, 36, 38, 40, 42 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin (USPN 4061738) and as evidenced by Aldrich (1994-1995, pp 866-867, 1075).

Martin discloses a flaxseed oil composition comprising 50% linolenic acid cis-cis (α-linolenic acid) and 15% linoleic acid (col. 4, line 60-col. 5, line 7). Also disclosed is a composition comprising 70% flaxseed oil in which the composition comprises 38% linolenic acid cis-cis (α-linoleic acid) and 30% linoleic acid (col. 6, lines 4-17). Administration of 15 mL of a compositions comprising the flaxseed oil for reducing platelet adhesiveness, reducing platelet aggregation and the suppression of thrombosis is disclosed (Abstract; col. 1, lines 13-20; col. 6, lines 19-26; col. 8, lines 20-27).

It is noted that the major components of the composition comprise linolenic acid, linoleic acid and oleic acid. As evidenced by Aldrich, these components have a density of about 0.9 g/mL. Accordingly, a 15 mL dose would be equivalent to about 13.5 g. The average individual is about 70 kg. Accordingly, administration of this composition to the average individual would be in a dose of about 0.19 g/kg, anticipating the instant claims.

It is further noted that the recitations of an "edible oil", "dietary supplement" and a "food composition" are preambles of the claimed composition. Accordingly, the recitations "edible oil", "dietary supplement" and "food composition" have not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not

depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). It is noted that the oil composition of Martin is, itself, an "edible oil", a "dietary supplement" and a "food composition".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27, 29, 35, 37, 39, 41, 43 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin and Aldrich as applied to claims 26, 28, 34, 36, 38, 40, 42 and 44 above and further in view of both Kobayashi et al. (EP 0435683) and Kraybill et al. (USPN 2353571).

Martin and Aldrich apply as disclosed above. Martin further teaches the addition of an oil fraction rich in phosphatides to the flaxseed oil composition described above (col. 5, lines 11-40; col. 7, lines 55-63). The references do not teach the addition of rapeseed and perilla oils.

Kobayashi et al. teaches the administration of an a-linolenic and/or linoleic acid oil for the reduction of platelent aggregation and the reduction of thrombosis (p. 2, lines 28-33 and 46-50). Such oils are selected from, e.g., perilla oil (p. 2, lines 46-50).

Kraybill et al. teaches rapeseed oil as a known source of phosphatides (col. 2, lines 35-52).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add perilla oil to the composition of Martin because (1) Martin is directed to a composition for reducing platelet aggregation and the inhibition of thrombosis; and (2) Kobayashi et al. teaches that perilla oil is known in the art to have an anti-platelet-aggregation effect and is effective in the prevention and treatment of thrombosis. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

It would have been obvious to one of ordinary skill in the art to add rapeseed oil to the composition of Martin because (1) Martin teaches the desirability of adding phosphatides to the composition; and (2) Kraybill et al. teaches rapeseed oil as a known source of phosphatides. One would have been motivated to add the rapeseed oil to the composition of Martin because the skilled artisan would have recognized rapeseed oil as interchangeable with the generic teaching of phosphatides in Martin. Accordingly, one would have had an expectation of success in preparing a composition suitable for reducing platelet adhesiveness, reducing platelet aggregation and the suppression of thrombosis.

Claims 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin, Aldrich, Kobayashi et al. and Kraybill et al. as applied to claims 27, 29, 35, 37, 39, 41, 43 and 45 above, and further in view of Ellenbogan et al. (USPN 3966920).

Martin, Aldrich, Kobayashi et al. and Kraybill et al. apply as disclosed above. Martin further teaches that administration of the compositions disclosed therein may be achieved via oral means, e.g., liquids and pills (Abstract; col. 8, lines 67-68). The references do not teach formulation as a capsule.

Ellenbogan et al. teaches compositions for the treatment of blood platelet aggregation (Abstract). Oral dosage forms of liquids, capsules and pills are taught to be interchangeable dosage forms therefor (col. 3, lines 47-62).

It would have been obvious to one of ordinary skill in the art at the time of the invention to formulate the composition of the combined references into a capsule because (1) Martin teaches the oral administration of the compositions disclosed therein for reducing platelet aggregation; (2) Martin teaches the oral administration of pills and liquids, specifically; and (3) Ellenbogan et al. teaches liquid formulations, pills, capsules, etc. as known in the art to be interchangeable the oral administration forms for the treatment of blood platelet aggregation. One would have been motivated to formulate the composition of the combined references as claimed because of an expectation of similar success in preparing a dosage form suitable for oral administration and, thereby, for reducing platelet aggregation.

Response to Arguments

Applicant's arguments with respect to Martin are not persuasive. Applicant argues, "Martin fail[s] to teach a composition/supplement as presently claimed wherein the composition/supplement is provided in a daily dose of 0.15 to 0.3 g/kg. The only mention of dose by Martin is 15 ml/day or at least 70% of the 15 ml/day." This argument is not persuasive because the daily dosage of 0.15 to 0.3 g/kg is of the *entire composition*, not just the flaxeed oil portion. Note that claim 26, for example, states that the "composition is provided in a daily dose of 0.15 to 0.3 g/kg", not that the flaxseed oil is provided in 0.15-0.3 g/kg or that the linolenic acid is provided in 0.15-0.3 g/kg. Accordingly, as discussed above, with a density of about 0.9 g/mL, the 15 mL composition would meet the current daily dosage claim limitations.

Applicant's arguments with regard to Leach (USPN 5612074) are not persuasive because the rejections pertaining thereto have been withdrawn in view of the amendments filed July 07, 2005.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER